

§ 482.56

42 CFR Ch. IV (10–1–07 Edition)

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

SOURCE: 72 FR 15273, Mar. 30, 2007, unless otherwise noted.

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation specified in §§ 482.1 through 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated

event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

End-Stage Renal Disease (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-Lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestine transplant center means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital (as defined in this rule) that provides

transplantation of a particular type of organ.

GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

(a) A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician;"

(2) A decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82;

(3) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(4) Inactivation of the transplant center.